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Evaluation of Medicines for Human Use

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COMMITTEE ON HERBAL MEDICINAL PRODUCTS (HMPC)

PROCEDURE ON MANAGEMENT OF PROPOSALS SUBMITTED BY INTERESTED PARTIES FOR COMMUNITY LIST ENTRIES OR COMMUNITY HERBAL MONOGRAPHS

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1. Purpose

The purpose of this document is to streamline and enable consistent management of proposals submitted by interested parties for:

- entries into the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (thereafter called the "Community list"),
- Community herbal monographs on traditional herbal medicinal products,
- Community herbal monographs on well-established herbal medicinal products.

The HMPC establishes the draft Community list and Community herbal monographs following assessment of scientific publications/data and in accordance with adopted procedures.
The number of substances/preparations under assessment is limited by the resources available at the level of the Committee and at the level of the national competent authorities in the EU Member States; prioritisation of the assessment work is therefore inevitable.
The HMPC is responsible for identifying the priority herbal substances/preparations/combinations to be covered by a list entry or a monograph. The process of identification of priorities carried out in the past years has resulted in the publication of two documents:

a) an alphabetic inventory[2] of herbal substances that the Committee intends to consider for assessment in the forthcoming years with a view to establishing a draft Community list entry and/or a Community herbal monograph;
b) an overview of status of assessment work[3] by the HMPC (so called 'priority list') providing, for approximately over 100 priority herbal substances, information as to whether
   - scientific data are being assessed by a Rapporteur (group R)
   - or the Rapporteur's assessment report is under discussion by the MLWP/HMPC (group D)
   - or a scientific opinion (in the format of a monograph and/or list entry) is under public consultation (group P)
   - or comments/new data that emerged from the public consultation are under assessment (group PF)
   - or a final scientific opinion has been adopted (group F)

   This overview is updated after each HMPC meeting to reflect the progress achieved.
   The preparation of draft monographs and list entries by the MLWP follows a workprogramme, which is established on an annual basis and is also published.

This document presents the procedure followed by the HMPC and its secretariat when documentation is submitted by an interested party with a view to including a given herbal substance, preparation or combination in the priority list of those herbal substances, preparations and combinations under assessment.

2. Scope

This procedure applies to the HMPC, the MLWP and to the HMPC secretariat for the management of proposals for Community list entries and Community herbal monographs.
The procedure does not apply to proposals concerning products, which have been used in the Community for less than 15 years, but are otherwise eligible for the simplified registration. Procedures for such products are handled by the national competent authorities of the Member States (referrals[4] under Article 16c(4) of Directive 2001/83/EC as amended).

[2] Published since October 2007

[3] Published since July 2006

[4] See Chapter 3 - Community Referral Procedures - of the Notice to Applicants Volumes 2A

3. Responsibilities

Members of the HMPC, MLWP and HMPC secretariat must ensure the adherence to this procedure in the management of proposals for Community list entries and for Community herbal monographs submitted by interested parties.

4. Templates needed for this procedure

The HMPC secretariat will seek to standardise its communication with interested parties and template letters will be used whenever possible.

5. Related documents

- HMPC Meeting dates (dates for HMPC meetings are published on the EMEA website)
- Template for a Community list entry (EMEA/HMPC/439705/2006 Rev. 2)
- Guideline on the documentation to be submitted for inclusion into the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/107399/2005 Rev. 1)
- Procedure for the preparation of an entry to the 'Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' (EMEA/HMPC/57137/2007)
- Template for a Community herbal monograph (EMEA/HMPC/107436/2005 Rev.4)
- Procedure for the preparation of Community monographs for traditional herbal medicinal products (EMEA/HMPC/182320/2005 Rev.2)
- Procedure for the preparation of Community monographs for herbal medicinal products with well-established medicinal use (EMEA/HMPC/182352/2005 Rev.2)
- Guideline on the assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations (EMEA/HMPC/104613/2005)
- Part II.1 of Annex I to Directive 2001/83/EC as amended

6. Definitions, abbreviations and references

Definitions

Community list entry = document whose purpose is to provide structured information, including information laid down in Article 16f(1) of Directive 2001/83/EC as amended, relating to specific herbal substances or herbal preparations or combinations of substances and preparations from a given plant[5] for use in traditional herbal medicinal products.

Community herbal monograph = document whose purpose is to provide a scientific summary of all data available on the safety and efficacy of a herbal substance/preparation intended for medicinal use, as referred to in Article 16h(3) of Directive 2001/83/EC as amended.

Interested parties: parties concerned with the use of medicinal products such as pharmaceutical industry associations, health care professional groups, scientific, consumers and patients' associations, governmental institutions as well as EU Member States and EEA-EFTA States.

Interested parties to the HMPC: specific interested parties identified[6] as having an interest in (traditional) herbal medicinal products at European level.

[5] It will be indicated if more than one plant is used and if hybrids are also used.

[6] http://www.emea.europa.eu/htms/human/hmpc/hmpcinterestedpart.htm

Abbreviations
EMEA = European Medicines Agency
HMPC = Committee on Herbal Medicinal Products
MLWP = Working Party on Community Monographs and Community List

7. Records

All documents, including correspondence, will be filed at the EMEA in the corresponding master binder (paper documents) and/or electronic file (specific "Community monographs/Community list" folder in "HMPC" folder). The HMPC secretariat shall track whether documents are available in paper and/or electronic format.
The HMPC secretariat will keep records of all proposals received with a view to monitoring the level of input from interested parties and reporting any substantial increase.

8. Instructions

8.1. Submission of proposal by interested parties

Interested parties are welcome to submit a proposal at any time. However, to ensure that a proposal is discussed by the HMPC at a specific meeting, the proposal must be received by the HMPC secretariat at least 4 weeks before the start of that meeting. If proposals are received within the 4 weeks preceding the start of a meeting, they may only be discussed by the HMPC at its next meeting.
The dates of HMPC meetings are published on the EMEA website.
Proposals can be submitted by any interested party or can be channelled through the identified 'Interested parties to the HMPC'.
Upon receipt at the EMEA, proposals from interested parties will be subject to the following steps:
- validation of the proposal by the HMPC secretariat
- review of the proposal by the MLWP and recommendation to the HMPC
- discussion and decision on priority by the HMPC
- interested party will be informed about the HMPC decision

8.2. Validation

The HMPC secretariat will verify that the proposal consists of the following set of documents:

a) the views of the interested party on the level of interest of the given herbal substance, preparation or combination, justifying that such substance, preparation or combination be added to the priority list for assessment by the HMPC; this should be a maximum 2-page document and may include information on Community interest, public health protection, market relevance, etc…;

b) supporting documentation to facilitate the future assessment by the HMPC, consisting of:
- a full bibliography after a comprehensive literature search, including a list of all references submitted. The documentation should also include a specification of the literature search strategy, the date of the search, search terms (inclusion/exclusion terms) as well as a listing of databases used for the search;
- overviews of non-clinical and clinical data supplemented by an Expert Report[7];
- a completed draft Community list entry or Community herbal monograph according to the latest template.

For proposals related to traditional use, the 'Guideline on the documentation to be submitted for inclusion into the Community list of herbal substances, preparations and combinations thereof for use in traditional herbal medicinal products' shall be referred to.
For proposals related to well-established use, the 'Guideline on the assessment of clinical safety and efficacy in the preparation of Community herbal monographs for well-established and of

[7] Prepared by suitably qualified and experienced persons (experts)

Community herbal monographs/entries to the Community list for traditional herbal medicinal products/substances/preparations' and Part II.1 of Annex I to Directive 2001/83/EC as amended shall be referred to.
As regard the documentation submitted, the requirements in terms of **copyright**, **confidentiality** and **language** are those laid down in the 'Procedure for calls for scientific data for use in HMPC assessment work' (EMEA/HMPC/1004/2006 Rev.1).

Documents can be submitted in paper or electronic (preferably) format. If paper, please note that 2 copies of all above-mentioned documents should be submitted to the HMPC secretariat (one copy kept at the Agency, one copy for the Rapporteur[8]).

The HMPC secretariat will acknowledge receipt of the validated proposal within two to three weeks from the submission of the documentation.

Interested parties that are not in the position to submit documents described under b) should provide a justification in the document required under a). If the omission of documents under b) is justified, the proposal will be validated.

8.3. Review of the proposal by the MLWP and recommendation to the HMPC

The MLWP will consider the views of the interested party on the level of interest and, if available, the list of all references submitted and the draft list entry or monograph; it will prepare a recommendation to the HMPC on the priority level.
The rest of the supporting documentation under b) will be considered as part of the assessment procedure that leads to the preparation of a list entry/monograph by the MLWP/HMPC.

8.4. Discussion and decision by the HMPC on priority

The Committee will consider the recommendation from the MLWP and take a decision.
If the Committee concurs with the interested party that the herbal substance, preparation or combination should be included amongst those substances/preparations/combinations to be assessed in priority by the HMPC, the proposal would be included in the priority list. This decision may result in the simultaneous appointment of a Rapporteur, if requests for Rapporteurship have been received from HMPC members. When a Rapporteur is appointed, the Rapporteur's appointment will be mentioned in the public report from the meeting. A call for (additional) scientific data may be published, if deemed necessary by the Rapporteur.
The priority list published on the EMEA website will be updated following the appointment of a Rapporteur. The HMPC secretariat will transmit one copy of the set of documents submitted by the interested party to the Rapporteur. The MLWP will be informed accordingly and systems to track assessment work at MLWP level will be updated. The assessment phase is initiated by the Rapporteur as soon as possible.
If the proposed herbal substance, preparation or combination is not added to the priority list, it will be added to the alphabetic inventory of herbal substances for future work, if not already included.

8.5. Interested party will be informed about the HMPC decision

The HMPC secretariat will inform the interested party of the HMPC decision. In case of a positive decision, the Rapporteur´s appointment and the estimated timetable for the assessment will be provided.

Remark:
Please note that requests for access to such proposals from interested parties will be handled in accordance with the Rules for the implementation of Regulation (EC) No 1049/2001 on access to EMEA documents.

[8] The Agency will keep the 2 copies until a Rapporteur is appointed.